CPRIT EARLY TRANSLATIONAL RESEARCH AWARD PROGRAM: OVERVIEW & FAQ

Overview

The Cancer Prevention and Research Institute of Texas (CPRIT) is initiating a new Early Translational Research Award (ETRA) mechanism to create a pipeline of promising new cancer products developed by the Texas academic community and to advance successful technology toward commercialization and company development. This new grant mechanism is open to Texas-based entities. Any not-for-profit institution that conducts research is eligible to apply.

The aim of the ETRA is to bridge the funding gap (sometimes referred to as the "valley of death") for the preclinical development of oncology products including:

- Small molecule therapeutics
- Cell therapy/biologic therapeutics
- Diagnostics
- Medical devices

How does the program work?

Early Translational Research Award applicants must be nominated for submission by an eligible Texas-based institution. Applicants can request up to $2M in total costs over a period of 1 to 2 years to support preclinical research and to develop a business plan. Applicants are encouraged to identify a co-PI with business acumen to provide this guidance.

Who is eligible to apply?

The applicant must be a Texas-based entity. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism. However, CPRIT is imposing a limit on the number of ETRA applications that may be submitted by an institution during this review cycle (see RFA section 8.2.14). A public or private company is not eligible for funding under this award mechanism; these entities must use the appropriate award mechanism(s) under CPRIT's Product Development Program.

NOTE: Applications for this award are subject to institutional caps. Applicants are advised to consult their Institution's Office of Research and Sponsored Programs (or equivalent).

Institutional limits (which need not to be fully used) are as follows: Baylor College of Medicine (3), The University of Texas M.D. Anderson Cancer Center (3), The University of Texas Southwestern Medical Center (3), Methodist Hospital Research Institute (2), Rice University (2), Texas A&M University (includes: Agrilife Research; Engineering Experiment Station) (2), The University of Texas at Austin (2), The University of Texas Health Science Center at Houston (2), The University of Texas Health Science Center San Antonio (2), Texas A&M University Health Science Center (2), Texas Tech University Health Sciences Center (2), The University of Texas Medical Branch Galveston (2), University of Houston (2), all others (1).

*How are awards made?

The selection process is the same as all other Academic Research RFA Mechanisms:

1. CPRIT will post the ETRA RFA on August 17, 2018
2. Application portal opens on October 17, 2018 and closes on January 30, 2019.
3. Applications submitted will undergo a full peer-review using a 2-stage peer review process: (1) Full peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council (SRC).
4. Applications recommended by the SRC will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the CPRIT Oversight Committee, portfolio balance across program, and available funding.
5. CPRIT's Oversight Committee votes to approve the applications recommended for funding.

**All dates listed above are tentative and may be subject to change. Please refer to CPRIT's website for official RFA release schedules and deadlines.*

What type of work does the ETRA Award fund?

The ETRA mechanism is designed to initiate the product development process for a promising technology that has a novel target and/or promises to address an unmet clinical problem and to move its development toward an investible technology and business opportunity. Typically, applicants for the ETRA award will have completed target validation and for therapeutics will have identified early hits and for a novel device have developed a prototype concept and for a diagnostic have identified a prototype test. Basic discovery research designed to identify or validate a new target or to support exploratory screening for new hit generation is not responsive to this RFA.

Examples of activities appropriate for the ETRA mechanism include (note this list is specific to therapeutics and not intended to be exhaustive):

- Lead optimization and identification of alternative lead series;
- Synthesize the optimized lead for *in vivo* efficacy, toxicity and PK/PD assessments;
- Evaluate activity in relevant preclinical models and demonstrate reproducible disease activity;
- Evaluate structure-activity relationships as related to disease specificity, potency, or formulation issues;
- Evaluate biopharmaceutical properties;
- Assess preclinical toxicology, PK and PD assessments;
- Evaluate biodistribution;
- Evaluate clinical readiness of PK/PD assay(s) and specimen handling SOPs;
- Assess feasibility of scale-up and bulk synthesis.

The ETRA program also supports development of medical devices and diagnostic technologies specific to cancer. Activities supported by the ETRA mechanism for device and diagnostic technologies include:

- System design, development, prototype fabrication and laboratory testing;
- Functional *in vitro* testing;
- Functional *in vivo* testing in relevant animal models;
- Toxicology and biocompatibility testing;
- Clinical correlations;
- Safety testing and failure modes analysis;
- Market research and physician input into product design;
- Competitive evaluation.

By the completion of the funding period a successful ETRA will have:

- Identified a novel therapeutic or diagnostic technology and shown a biological effect;
- Convincing, statistically significant, reproducible disease modifying activity in a relevant preclinical model(s) that is comparable or better than standard-of- care therapy;
- Conducted preliminary safety & toxicology testing (in the case of therapeutic agents);
- Shown the product can be manufactured at small scale or as a prototype;
- Assessed the business opportunity addressing clinical utility, target market, financial plan, IP strategy, etc.;
- Initiated a patent application.

Which project expenditures will the ETRA Award reimburse?

- Funds may be used for salary and fringe benefits, research supplies, equipment, *in vitro* and *in vivo* studies, and travel to scientific/technical meetings or collaborating institutions.
- Funds may be requested for salary and fringe benefits to support a co-PI with the business expertise to aid in completing detailed market analysis, business plans, and product development strategies.
- Funding is also available to support access to good laboratory practice, good clinical practice, and regulatory expertise; to provide access to specialized technical infrastructure; and to develop a level of oversight and management that may be beyond the reach and experience of those conducting the research.
- Requests for funds for research services outsourced on a contract basis to a contract research service provider are appropriate if the need is well documented, justified and cost effective.

For more information, please visit www.cprit.texas.gov or contact:

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